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In re Application of Daniel O'Mahony and Michela Seveso Application No. 09/443,780

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<u>Amendments</u>

In the Claims

- (Currently amended) An isolated antibody or antibody fragment specific to a domain
 of a gastro-intestinal tract (GIT) targeting agent, said targeting agent comprising
 ZElan033 (PAX2 15 mer) (SEO ID NO:1) a protein that specifically binds to a GIT
 receptor.
- (Original) The antibody or antibody fragment of claim 1, wherein the antibody or antibody fragment is selected from the group consisting of a polyclonal antibody, monoclonal antibody, chimeric antibody, single chain antibody, a Fab fragment or a Fab expression library.
- 3. (Cancel) The antibody or antibody of fragment of claim 1, wherein the GIT targeting agent is selected from the group consisting of ZEIan033 (PAX2 15 mer) (SEQ ID NO:1), ZEIan088 (HAX42-2 20 mer) SEQ ID NO:2) or ZEIan053 (P31 D-form 16 mer) (SEQ ID NO:3).
- 4. (Withdrawn) A method of making an antibody of antibody fragment of claim 1, comprising the steps of (a) contacting a GIT targeting agent with the immune system of an animal under conditions conducive to formation of antibodies in abody fluid of the animal and (b) recovering the antibody or antibody fragment from the body fluid of the animal.
- 5. (Withdrawn) A method of identifying the presence of a GIT targeting agent in a composition or quantitating the amount of a GIT targeting agent in a composition, wherein the composition comprises the GIT targeting agent bound to an active agent, comprising the steps of (a) contacting an antibody or an antibody fragment specific to a domain of the GIT targeting agent with the composition under conditions conducive to binding between the antibody or antibody fragment and the GIT targeting agent; and

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(b) detecting the amount of antibody or artibody fragment that specifically binds to the GIT targeting agent.

- 6. (Withdrawn) A method of identifying the location of a GIT targeting agent in a composition, wherein the composition comprises the GIT targeting agent bound to an active agent, comprising the steps of (a) contacting an antibody or antibody fragment specific to a domain of the GIT targeting agent; and (b) visualizing the position of the antibody or antibody fragment that specifically binds to the GIT targeting agent.
- 7. (Withdrawn) The method fo Claim 6, wherein the composition comprises an active agent loaded nano- or microparticle bound to the GIT targeting agent.
- 8. (Withdrawn) A method of identifying the location of a GIT targeting agent following contact of a GIT targeting agent-containing composition with human or animal gastro-intestinal tissue, comprising the steps of (a) contacting an antibody or an antibody fragment specific to a domain of the GIT targeting agent with the composition under conditions conducive to binding between antibody or antibody fragment and the GIT targeting agent; and (b) detecting the location of the antibody or antibody fragment that specifically binds to the GIT targeting agent.
- 9. (Withdrawn) An antibody or antibody fragment of Claim 1, wherein the GIT transport receptor is selected from the group consisting of D2H (domain 387-685) (SEQ ID NO:13), hS1 (domain 272-667) (SEQ ID NO:14), HPT1 (domain 29-273) (SEQ ID NO:15), and hPEPT1 (domain 391-571) (SEQ ID NO:16).
- 10. (Withdrawn) An antibody or antibody fragment of claim 9, wherein the protein comprises either an amino acid sequence selected from the group consisting of SEQ ID NOS: 17-71 or a receptor binding portion of the amino acid sequence.

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- 11. (Withdrawn) An antibody or antibody fragment of claim 10, wherein the protein consists of the amino acid sequence selected from the group consisting of SEQ ID NOS: 17-71 or a receptor binding portion of the amino acid sequence.
- 12. (Withdrawn) An antibody or antibody fragment of claim 10, wherein the protein comprises the amino acid sequence selected from the group consisting of SEQ ID NOS:
- 13. (Withdrawn) An antibody or antibody fragment of claim 11, wherein the protein consists of the amino acid sequence selected from the group consisting of SEQ ID NOS: 17-71.
- 14. (Withdrawn) An antibody or antibody fragment of claim 9, wherein the protein consists of an amino acid sequence of not more than 50 amino acids in length, the amino acid sequence is one selected from the group consisting of
 - (a) Xaa₁ Thr Xaa₂ Xaa₃ Ser Xaa₄ Xaa₅ Xaa₆ Asn Xaa₇ Arg (SEQ ID NO: 72), where Xaa₇ is Ser or Thr; Xaa₂ is Arg or Lys; Xaa₃ is Lys or Arg; Xaa₄ is Ser or Leu; Xaa₅ is Arg, Ile, Val, or Ser Xaa₆ is Ser, Tyr, Phe, or His; and Xaa₇ is Pro, His or Arg;
 - (b) Asp Xaa₁ Asp Xaa₂ Arg Arg Xaa₃ Xaa₄ (SEQ ID NO: 73) where Xaa₁ is Ser, Ala, or Gly; Xaa₂ is Val or Gln; Xaa₃ is Pro, Gly, or Ser, and Xaa₄ is Trp or Tyr;
 - (c) Val Arg Ser Gly Cys Gly Xaa₁ Xaa₂ Ser Ser (SEQ ID NO: 74), where Xaa₁ is Ala or Phe; and Xaa₂ is Arg or His;
 - (d) NTRKSSRSNPR (SEQ ID NO: 75);
 - (e) STKRSLIYNHR (SEQ II) NO: 76);
 - (f) STGRKVFNRR (SEQ ID NO: 77);
 - (g) TNAKHSSHNRR (SEQ D NO: 78);
 - (h) DSDVRRPW (SEQ ID NO: 79);
 - (i) AADQRRGW (SEQ ID/NO: 80);
 - (j) DGRGGRSY (SEQ \square NO: 81);
 - (k) RVRS (SEQ ID NO: \$2);



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- (I) SVRSGCGFRGSS (SEQ D NO: 83);
- (m) SVRGGCGAHSS (SEQ D NO: 84).
- 15. (Withdrawn) An antibody of claim 1.
- 16. (Withdrawn) An antibody of claim 2.
- 17. (Withdrawn) An antibody of claim 3.
- 18. (Withdrawn) An antibody of claim 9.
- 19. (Withdrawn) An antibody of claim 10.
- 20. (Withdrawn) An antibody of claim 11.
- 21. (Withdrawn) An antibody of claim 12.
- 22. (Withdrawn) An antibody of claim 13.
- 23. (Withdrawn) An antibody of claim 14.
- 24. (Withdrawn) An antibody or antibody fragment, said antibody or antibody fragment capable of immunospecifically binding to a protein, said protein being capable of specific binding to a GIT transport receptor.
- 25. (Withdrawn) An antibody or antibody fragment of Claim 24, wherein the antibody or antibody fragment is selected from the group consisting of a polyclonal antibody, monoclonal antibody, chimeric antibody, single chain antibody, a Fab fragment or a member of a Fab expression library.



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- 26. (Withdrawn) An antibody or antibody fragment of claim 24, wherein the protein consists of an amino acid sequence selected from the group consisting of ZElan033 (PAX2 15 mer) (SEQ ID NO:1), ZElan088 (HAX42-2 20 mer) (SEQ ID NO:2) or ZEIan053 (P31 D-form 16 mer) (SEQ ID NO:3).
- 27. (Withdrawn) An antibody or antibody fragment of Claim 24, wherein the GIT transport receptor is selected from the group consisting of D2H (domain 387-685) (SEQ ID NO:13), hS1 (domain 272-667) (SEQ ID NO:14), HPT1 (domain 29-273) (SEQ ID NO:15), and hPEPT1 (domain 391-571) (SEQ ID NO:16).
- 28. (Withdrawn) An antibody or antibody fragment of claim 27, wherein the protein comprises either an amino acid sequence selected from the group consisting of SEQ ID NOS: 17-71 or a receptor binding portion of the amino acid sequence.
- 29. (Withdrawn) An antibody or antibody fragment of claim 28, wherein the protein consists of the amino acid sequence selected from the group consisting of SEQ ID NOS: 17-71 or a receptor binding portion of the amino acid sequence.
- 30. (Withdrawn) An antibody or antibody fragment of claim 29, wherein the protein comprises the amino acid sequence selected from the group consisting of SEQ ID NOS: 17-71.
- 31. (Withdrawn) An antibody or antibody fragment of claim 27, wherein the protein consists of the amino acid sequence selected from the group consisting of SEQ ID NOS: 17-71.
- 32. (Withdrawn) An antibody or antibody fragment of claim 24, wherein the protein consists of an amino acid sequence of not more than 50 amino acids in length, the amino acid sequence is one selected from the group consisting of
 - (b) Xaa, Thr Xaa, Xaa, Ser Xaa, Xaa, Xaa, Asn Xaa, Arg (SEQ ID NO: 72), where Xaa, is Ser or Thr; Xaa, is Arg or Lys; Xaa, is Lys or Arg; Xaa, is Ser





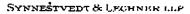
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or Leu; Xaa, is Arg, Ile, Val, or Ser; Xaa, is Ser, Tyr, Phe, or His; and Xaa, is Pro, His or Arg;

- (b) Asp Xaa₁ Asp Xaa₂ Arg Arg Xaa₃ Xaa₄ (SEQ ID NO: 73) where Xaa₁ is Ser, Ala, or Gly; Xaa₂ is Val or Gln; Xaa₃ is Pro, Gly, or Ser; and Xaa₄ is Trp or Tyr;
- (c) Val Arg Ser Gly Cys Gly Xaa₁ Xaa₂ Ser Ser (SEQ ID NO: 74), where Xaa₁ is Ala or Phe; and Xaa₂ is Arg or His;
- (d) NTRKSSRSNPR (SEQ ID NO: 75);
- (e) STKRSLIYNHR (SEQ ID NO: 76);
- (f) STGRKVFNRR (SEQ ID NO: 77);
- (g) TNAKHSSHNRR (SEQ ID NO: 78);
- (h) DSDVRRPW (SEQ ID NO: 79);
- (i) AADQRRGW (SEQ ID NO: 80);
- (j) DGRGGRSY (SEQ ID NO: 81);
- (k) RVRS (SEQ' ID\ NO:/82);
- (1) SVRSGCGFRGSS (SEQ ID NO: 83);
- (m) SVRGGCGAHSS (SEQ ID NO: 84).
- 33. (Withdrawn) An antibody of claim 24.
- 34. (Withdrawn) An antibody of claim 25.
- 35. (Withdrawn) An antibody of claim 26.
- 36. (Withdrawn) An antibody of claim 27.
- 37. (Withdrawn) An antibody of claim 28.
- 38. (Withdrawn) An antibody of claim 29.





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39. (Withdrawn) An antibody of claim 30.

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40. (Withdrawn) An antibody of claim 31.

41. (Withdrawn) An antibody of claim 32.